

Patient Safety Alert

Veterans Health Administration Warning System
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December 21, 2005

Item: Injector connector relays on patient tables manufactured by Philips Medical, table models AD5 and AD6 used with the Integris, Integris Allura and Allura Xper x-ray systems.

Specific Incident: The manufacturer reports failures of Injector connector relays for the table models listed, although none are reported in VA. If a relay fails, high voltage can be present on a pin of the exposed injector connectors, placing patients and employees at risk. Philips will be upgrading affected systems as parts are available, to be completed by mid-2006. Philips Medical has identified 42 VA medical facilities affected by this Alert

Action: If affected and you have not already done so:

1. Within one week, identify affected tables, and until the tables are upgraded,
2. Cover the connectors (diagrams in attached Philips notification) with nonconductive material, and
3. Inform users to exercise caution when connecting/disconnecting the injector connector from the table and when cleaning near the connector.

Addl. Information: Contact VA Center for Engineering & Occupational Safety and Health (CEOSH) if you are affected and did not receive Philips' letter.

Source: CEOSH, Manufacturer and FDA

Contact: Sarah Baxter, Director, Regulatory Affairs, Philips Medical
at (425) 487-7665

Paul Sherman, VA Center for Engineering & Occupational Safety and Health (CEOSH) at (314) 543-6700



**PRODUCT SAFETY NOTIFICATION
via Certified Mail - Return Receipt Requested**

October 10, 2005

Subject: User Notification, Injector Connector on AD5/6 Table, FCO 72200063

Dear Director of Cardiology:

Philips Medical Systems would like to inform you of a potential situation (high voltage exposure) involving the injector interface connector on our AD5 and AD6 patient support tables. As you may know, each table is equipped with an injector interface connection plug, located on the connection box at the rear base of the table. This allows for easy coupling of the injector to the X-ray system. This connection plug also supplies mains power (230V) to the injector.

Under normal circumstances, the mains power (230V) is only present on the connector when an injector plug is inserted. The injector plug itself provides complete isolation when inserted. However, if the connector relay switch were to fail, this voltage may become present on the connector, whether an injector is plugged in or not. Such a scenario is possible on all AD5 and AD6 patient tables supplied with Philips Integris, Integris Allura and Allura Xper Systems.

Philips will be performing a mandatory upgrade to correct for this situation. This correction will be performed at no cost to you. Installation of this upgrade is expected to begin during Q4 2005 and should be completed by the end of Q3 2006.

Since the injector connector plug is normally exposed when not in use, we advise you to cover it with a nonconductive material (such as a plastic cap, for example) when unplugged, or if not utilized. This will minimize the risk of accidental contact, until Philips can provide a permanent modification. Please instruct all personnel to be cautious when (un) plugging the injector into the table base, as well as when cleaning (avoid wiping area around connector unless well covered). Additional diagrams are supplied on Exhibit 1 and are attached with this letter to help you identify the location of the connector plug in question.

We apologize for any inconvenience this may represent and appreciate your forwarding this information to the appropriate individuals within your organization. If you have any questions, please feel free to contact me at 425-487-7665.

Sincerely,

A handwritten signature in cursive script that reads "Sarah Baxter".

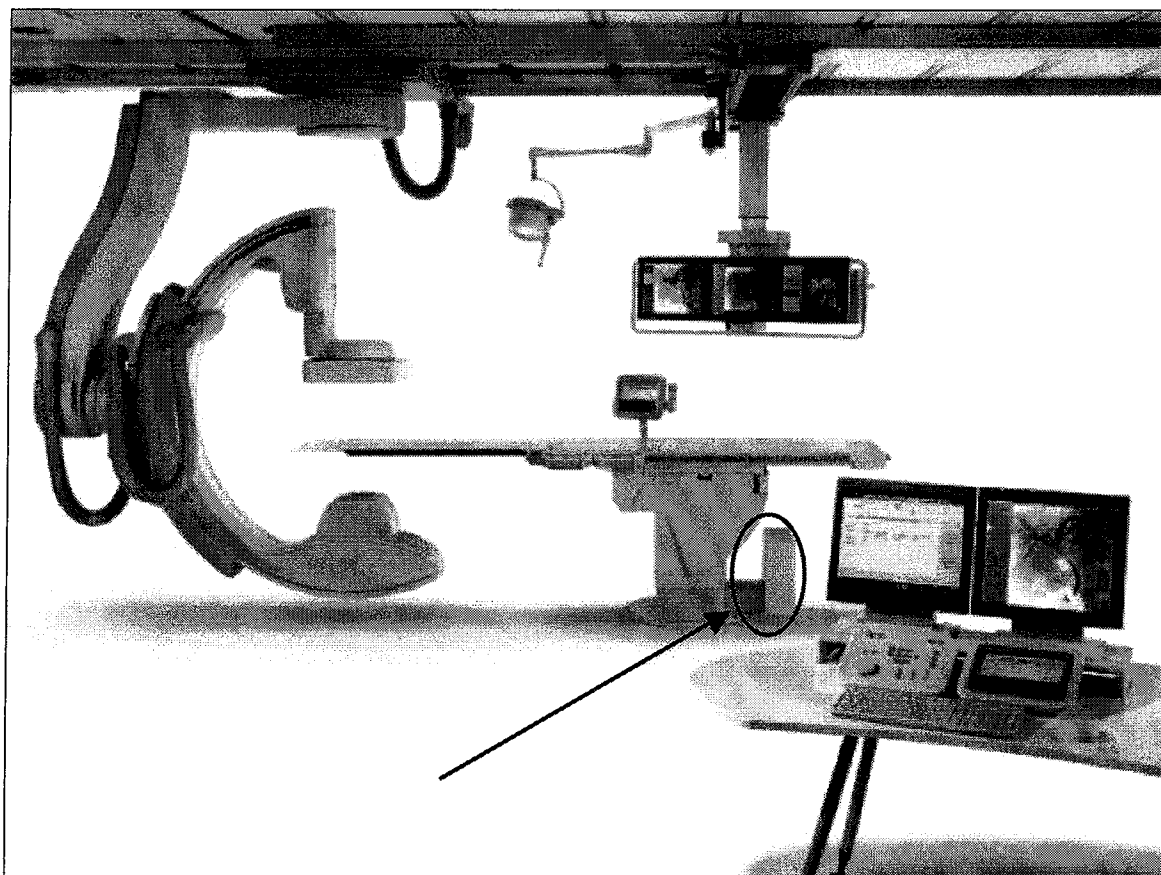
Sarah Baxter
Director, Regulatory Affairs

Enclosure: Exhibit 1, AD5 and AD6 Injector Plug Diagrams

User Notification, Injector Connector on AD5/6 Table, FCO 72200063

Exhibit 1: AD5 and AD6 Injector Plug Diagram

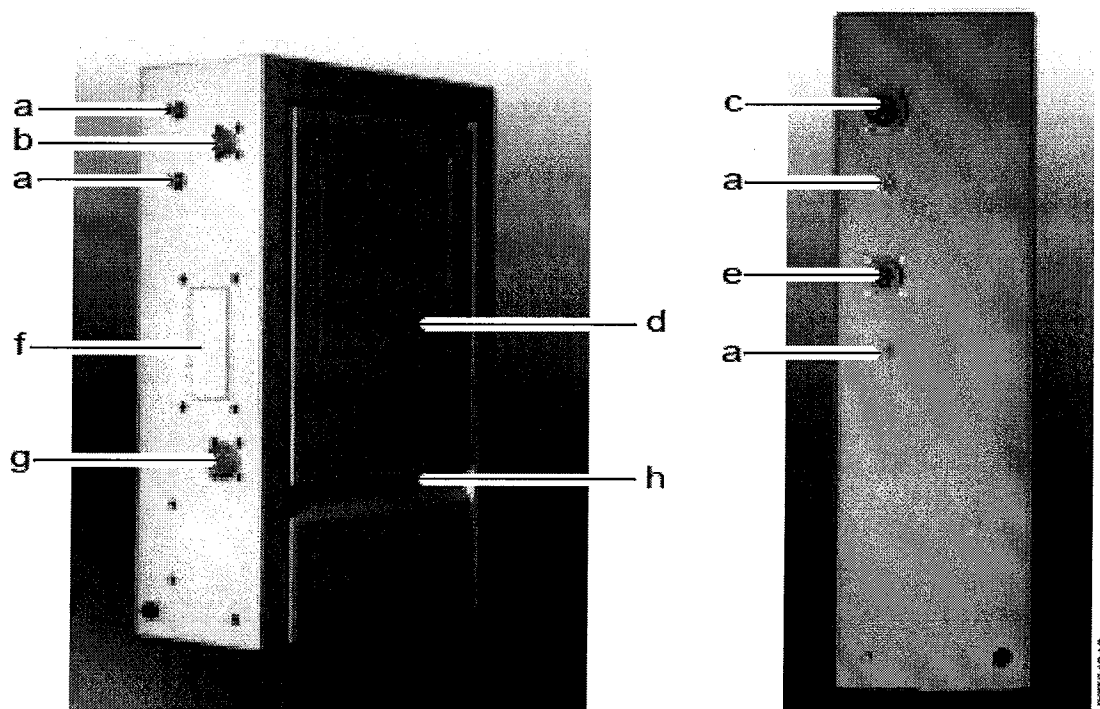
AD5 and/or AD6 Connection Boxes are located at backside of Patient Support (table), as shown by the red arrow and circle. The actual connector in question (provided for use with injectors) is located on the Nurse's side of the Patient Support. See other pictures below for detail.



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The connection box shown here is for an **AD5** table (Patient Support). The connector in question is noted as “**c**”.

Connection box (at back of patient support)



Item	Connections
a	Earth (ground).
b	X-ray hand switch.
c	Injector.
d	Prepared for local mains connection.

The connection box shown here is for an **AD6** table (Patient Support). The connector in question is noted as “2”.

4.23 Tablebase Connection Box

The table base connection box is located under the table top at the rear of the table base. The connection box allows to connect different types of additional equipment to the system.

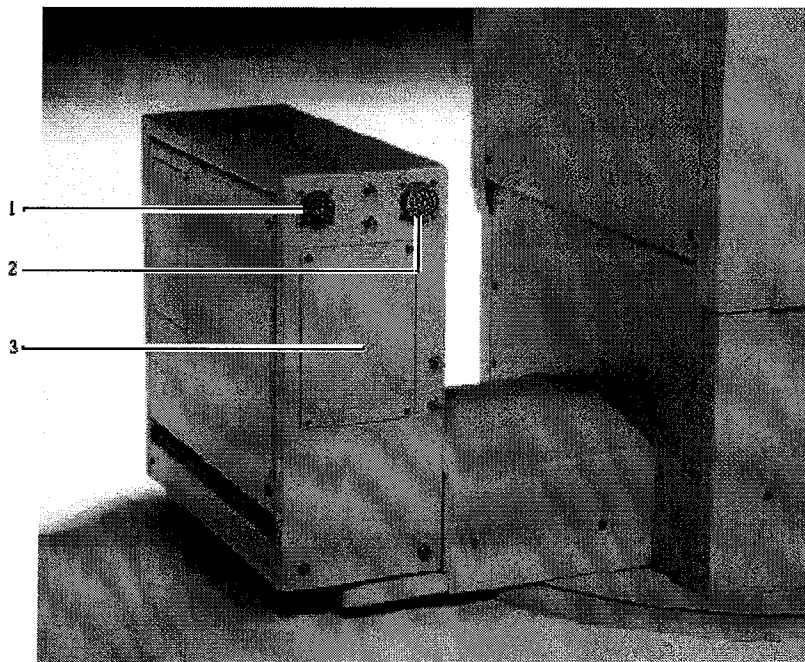


Figure 4.106 Table base connection box

Connection of additional equipment:

- [1] 23-pin Burndy connector
Connector for external ECG and Physio equipment.
- [2] 28-pin Burndy connector
Connector for external pedestal injector.
- [3] Connector instead of cover plate (not physically shown)
Instead of the cover plate, a connector can be located here that allows to connect various types of rack-mounted injectors.